PETITION FOR EXTENSION OF TIME

Pursuant to 37 C.F.R. § 1.136(a), Applicant petitions for an extension of time of three months, to and including February 13, 1999, in which to respond to the Office Action dated August 13, 1998. Pursuant to 37 C.F.R. § 1.17, a check in the amount of $435.00 is enclosed, which is the process fee ($435.00) for a three-month extension of time. If the check is inadvertently omitted, or should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, or should an overpayment be included herein, the Assistant Commissioner is authorized to deduct or credit said fees from or to Arnold, White & Durkee Deposit Account No. 01-2508/UTXC:538/HYL.

REMARKS

I. Status of Claims

Claims 29-47 are pending, claims 1-28 and 48 having been canceled previously. Claims 29-47 are rejected under 35 U.S.C. §112, first paragraph and §112, second paragraph. The specific grounds for rejection, and applicants response thereto, are set out in detail below.

II. Formalities

The examiner has requested a copy of the drawings. These are attached this response. The examiner also notes a discrepancy between the number of sequences in the resubmitted sequence listing. However, applicants' copy of the resubmitted listing has 46 sequences indicated and 46 sequences included. Applicants have included a copy of the last page of the sequence listing, as previously provided, which contains the 46th sequence.

III. Rejection Under 35 U.S.C. §112

Claims 29-47 stand rejected on both the first and second paragraphs of §112. Since both rejections turn on the same issue - the introduction of the term "directly inhibiting HIV entry into a cell" - these rejections will be addressed together.

As indicated in the previous response, the present invention is directed at the use of particular gp120-derived peptides to block the infection of cells by HIV-1. This embodiment is described, for example, at page 14 of the original specification:

> As used herein, the term "HIV infection-inhibiting sequence" refers to a peptide sequence which prevents entry of the HIV virus into its target cell. As such, an inhibitory peptide may be characterized as including a peptide sequence that is involved in the infection process, or that functions to contact the target cell. Infection-inhibiting peptides particularly include peptides that comprise a sequence wherein antibodies against that sequence are capable of inhibiting HIV cellular infection.

> The present invention discloses that synthetic peptides with sequences derived from the HIV-1 *env* gene product, gp120, have the capacity to inhibit HIV cellular infection. In particular, the inventors have identified HIV infection-inhibiting sequences within the V3 loop and at the N-terminal regions of gp120. It is also contemplated that HIV infection-inhibiting sequences may prove to be located within the CD4 binding region.

Thus, it should be clear that the present invention does not rely on the immune system in order to effect blocking of viral infection.

The examiner now has balked at the amendments which sought to clarify the use of peptides as agents that directly (*i.e.*, non-immunologically) inhibit HIV infection of cells. The entire basis of these rejections is that the application does not support non-immunologic uses of these peptides.

However, as pointed out above, the specification clearly indicates infection-inhibiting peptides ***include*** those which induce antibodies. This indicates that the peptides encompass other peptides as well. Applicants believe that the quotation above, not the examiner's selective paraphrasing, illustrates the scope of the invention.

However, even more clear support for the claims as amended comes from Example 8 of the specification. There, peptides are shown to inhibit infection of cells *in vitro*. ***By definition,***

there can be no immune functions at work in these experiments. Thus, there is absolutely no doubt that one of skill in the art would read the specification as supporting the instant claims. It also is stated at page 70 that ***two*** different mechanisms are at work - T cell induction and inhibition of entry.

In addition, the discussion of direct-blocking methods concludes, at page 18, by stating that "it is contemplated that peptides which do ***not*** induce the significant production of antibodies that bind to native HIV will be employed" (emphasis added). This is, again, a clear indication that non-immune mechanisms are part of the invention. Page 29 states that "in addition to vaccine formulations, the inventors have also identified peptide sequences which function to effectively inhibit the entry of HIV into human target cells." These non-vaccine formulations clearly are not directed to the induction of cellular or antibody response (see page 42 where vaccines are said to be formulated in amounts that are "immunologically effective"). Moreover, the clear statement is that the ***peptides***, not antibodies produced thereagainst, inhibit infection. There are numerous other passages throughout the specification that clearly are addressed to direct blocking by peptides as well.

It is true that the specification ***also*** supports the use of peptides to induce both humoral and cellular immune responses. This is in no way "contradictory" with applicants' previous

response, and the examiner has not provided any reasoning to support this statement. Rather, the application simply addresses different embodiments, and the embodiment which now is being claimed is well-supported as described above.

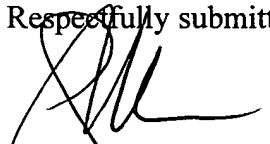
With regard to the definiteness issue, applicants believe that the acknowledgement of the enabling support for "direct" blocking also will address the §112, second paragraph issues.

In sum, while the specification addresses different embodiments, there is clear support, both for the meaning and implementation, of direct blocking of infection. Applicants respectfully request that the examiner carefully review the cited passages, and the specification as a whole, and withdraw the rejection in light of this review.

VI. Conclusion

In light of the foregoing amendments and remarks, applicants respectfully submit that all claims are in condition for allowance and an early indication to that effect is earnestly solicited. Should Examiner Smith have any questions regarding this response, she is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,



Steven L. Highlander
Reg. No. 37,642

ARNOLD, WHITE & DURKEE
P. O. Box 4433
Houston, Texas 77210
(512) 320-7200

Date: 2/12/99

(2) INFORMATION FOR SEQ ID NO:46:

(i) SEQUENCE CHARACTERISTICS:
(A) LENGTH: 16 amino acids
(B) TYPE: amino acid
(C) STRANDEDNESS:
(D) TOPOLOGY: linear

(xi) SEQUENCE DESCRIPTION: SEQ ID NO:46:

Lys	Gln	Ile	Ile	Asn	Met	Trp	Gln	Glu	Val	Gly	Lys	Ala	Met	Tyr	Ala
1				5					10						15